SOPP 8503.2
Review of Import For Export Requests Under Section 801(d)(4) of the FD&C Act

APPENDIX 2

Sample approval letter

Name **Reference Number:**
Title
US Import for Export Requester
Address
City State Zip

Dear **Name** :

This letter is to inform you that your Import for Export request is approved. Your letter, dated , and additional information dated, requested that the Center for Biologics, Evaluation and Research (CBER) make a determination to allow for **US Firm Name** and **Foreign Firm Name** to import **Imported Product Name** for further processing. This imported **Imported Product Name** will be processed into **Final Product Name** for subsequent export, pursuant to section 801(d)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

Please update your registration and listing to reflect products being manufactured. The listing should include the imported article as well as the final product for export.

Product being exported pursuant to section 801(d)(4) must comply with the applicable requirements of section 801(e)(1) or 802 of the act or section 351(h) of the Public Health Service Act. These statutory provisions may impose additional requirements such as notification, labeling, and recordkeeping.

The import statement should include a copy of this letter to facilitate the entry of the unlicensed blood products.

Sincerely yours,

Steven A. Masiello
Director
Office of Compliance and
Biologics Quality
Center for Biologics Evaluation
and Research

CC: **Name**
Title
Foreign Manufacture
Address

Bcc: HFR- **District Director**
GCF-1 (M. Raza)
GCF-1 (P. Kaeding)
HFM-600/601
HFM-624 Read file
HFM-30 (E. Esber)

DOC: **FY2000**-IFER Name of US Firm – Name of Foreign Firm IFE approval letter.doc**